DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 114300 (718) 340-7000 Industry Information: www.fda.gov/oc/industry	02/17/2014 - 02/27/2014
	FEI NUMBER 1000120311

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Yigang Song, Quality Systems Manager

FIRM NAME	STREET ADDRESS
Medisca Inc.	661 State Route 3
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Plattsburgh, NY 12901	API Repacker

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM I (WE) OBSERVED:

1. Examination and testing of incoming materials is not completed.

Specifically, at least one test to verify the identity of each batch or material was not conducted. Your firm failed to verify identity of eight lots of L-Citrulline manufactured by (b) (4) and received at your firm between April 5, 2013 and February 3, 2014. (b) (4) Lot #(b) (4) was repacked as Medisca Lots #95482 and #96453 on 4/16/13 and 5/28/13, respectively, which was further distributed, including compounding pharmacies. Subsequently, several complaints were received on lots #95482 and #96453. Identity testing confirmed the lots as N-Acetyl-Leucine. Medisca lot numbers #95482 and #96453 were recalled on February 14, 2014.

2. Investigations of customer complaints are inadequate in that they did not extend to other batches of drug substances that may have been associated with a specific failure or discrepancy or conduct root cause analysis.

Specifically, your firm failed to conduct comprehensive investigations to determine the root cause/ source in response to complaints received for repackaged L-Citrulline, Lot #95482 and Lot #96453. Complaints that L-Citrulline did not meet organoleptic description on product label were received on June 20, 2013 (Lot #95482) and October 16, 2013 (Lot #96453), however a thorough investigation was not initiated until February 7, 2014, after additional customer complaints. The investigation identified Out-of-Specification solubility results for a single manufacturer's lot, (b) (4) repackaged into Medisca Lot #95482 and Lot #96453, which were recalled on February 14, 2014.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Chad N. Thompson	Chad N. Thompson, Investigator	02/27/2014

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3. Authentic Certificates of Analysis were not issued for each batch of API. Specifically,

a. Medisca Certificate of Analysis for L-Citrulline Lot #95482 was created and approved in April 8, 2013. Using this Certificate of Analysis as a template, Certificates for subsequent repackaged batches (Lot #96453, 98655, 100219, and 47094) of L-Citrulline were prepared using the same product specifications. (b) (4) test method, (b) (4) appears on the Certificates of Analysis for all of these batches however, identification verification by (b) (4) was not completed for any of these batches.

b. Certificates of Analysis for L-Citrulline, Lot #95482, 98655, 100219, and 47094 do not reference the name and address of the original manufacturer, (b) (4) nor do they include a copy of the original batch Certificate.

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